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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/963,878 | 09/26/2001 | Bruce S. Ellingboe | CV-0290US | 9174 |
| 9561 | 7590 | 08/11/2004 | EXAMINER | |
| POPOVICH, WILES & O'CONNELL, PA 650 THIRD AVENUE SOUTH SUITE 600 MINNEAPOLIS, MN 55402 | | | DEAK, LESLIE R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3762 | |

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,878

Applicant(s)

ELLINGBOE ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4 and 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,462,416 to Dennehey et al in view of US 5,385,540 to Abbott. . Dennehey discloses a blood pumping cassette within a blood circuit with a plurality of tubing lines (134, 136) that connect to fluid passageways within the cassette. The cassette is comprised of a rigid portion connected to a flexible portion. (See FIG 9; column 6.) The blood circuit further comprises a control unit with a component interface region and an area that interfaces with the cartridge, and a pump. (See FIG 76; column 20.) The system further comprises blood reservoirs (see column 16, lines 40-45), flow control clamps, air bubble detectors (see column 10, lines 25-35). The cassette further comprises pressure sensors and valve stations that are actuated to regulate fluid flow (see columns 6-7).

Abbot discloses a blood circuit with a cassette that serves to control fluid flow in a cardioplegia circuit. Use of the cassette serves to simplify the fluid control, preventing the operator from having to manually set up the fluid channels in the complicated circuit. Abbot discloses that the system incorporates an oxygenator 14, pumps in the pump cassette that send fluid from the oxygenator

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through the rest of the circuit back to the patient, and a cardioplegia circuit that combines blood and cardioplegia solution in the circuit (see columns 3-4). Abbot fails to disclose the tubing lines, valves, and sensors as claimed, but Dennehey, as delineated above, disclosed those claimed limitations. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add the tubing lines, valves, and sensors, along with the other claimed limitations found in the Dennehey device, to the cassette disclosed by Abbott in order to provide a simplified, controllable cardioplegia fluid circuit, as taught by Abbot.

With regard to applicant's claim limitations drawn to the functions of the blood circuit, the pump, the reservoir, flow control clamp, sensors in the claims, the claims recite the functions of the devices in narrative form, and such recitations have not been given patentable weight. In order to be given patentable weight, a functional recitation must be expressed as a "means" for performing the specified function, as set forth in 35 USC 112, 6th paragraph, and must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language.

3. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,462,416 to Dennehey et al, in view of US 5,820,579 to Plotkin, in view of US 5,385,540 to Abbott. Dennehey discloses the blood circuit and cassette as claimed including an air detector, but fails to disclose a valve with diverting mechanism. It is well known within the art of blood processing to provide air detectors and divert blood with bubbles in it so as not to introduce air bubbles into the patient, as taught by Plotkin. Plotkin discloses a cardiopulmonary bypass

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circuit with a pump and an oxygenator and an air detector 36. When the air detector senses a bubble in the line, microprocessor/controller 50 employs valve 38 to divert the blood and air bubble into recycle line 48, which serves as a reservoir, in order to prevent the air bubble from being introduced to the patient. Plotkin discloses that his system is better than conventional air trap systems, since the diverting technique diverts a minimum amount of fluid while maintaining adequate blood output to the patient (see column 4). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add a diverting mechanism to the cassette and air sensor of the Dennehey/Abbot device in order to prevent introduction of air to the patient while maintaining adequate blood flow in the system.

Response to Arguments

4. Applicant's arguments filed 7 April 2004 have been fully considered but they are not persuasive.
5. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the combined references do not teach away from

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one another as argued by applicant. Rather, looking at the Dennehey reference (or the combination of Dennehey and Plotkin) in view of Abbot merely suggests improvements to the Dennehey device, since Abbot specifically contemplates embodiments found in the Dennehey device and improves upon them.

Furthermore, examiner is not combining the references to show any compatibility between the pumping systems of the two references. Rather, examiner has found another reason for combining the references, namely the presence of the oxygenator in the Abbott device. Therefore, the references are properly combined.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lrd
3 August 2004



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